BEFORE THE STATE BOARD OF PHARMACY STATE OF MISSOURI

| MISSOURI BOARD OF PHARMACY, |) |
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| Petitioner, |) |
| V. |) Case No. 2011-001707-V1 |
| MOBERLY PROFESSIONAL ARTS PHARMACY, INC., d/b/a BUNTINS PHARMACY, |))) |
| Respondent. | Ś |

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER OF DISCIPLINE

This matter appears before the Missouri Board of Pharmacy (hereinafter "Board") pursuant to a violation of discipline Complaint regarding Respondent Moberly Professional Arts Pharmacy, Inc., d/b/a Buntins Pharmacy (hereinafter "Buntins").

Findings of Fact

- 1. The Board set this matter for hearing and served notice of a violation of discipline hearing upon Buntins based upon a Complaint alleging violations of a Settlement Agreement Between State Board of Pharmacy and Moberly Professional Arts Pharmacy Inc., d/b/a Buntins Pharmacy (hereinafter "Settlement Agreement") executed between the Board and Buntins.
- 2. Pursuant to notice and Section 621.110, RSMo, this Board held a hearing on January 18, 2012, at the Courtyard by Marriott, Columbia, Missouri, for the purpose of determining the appropriate disciplinary action against the pharmacy permit of Buntins. William Buntin, owner and pharmacist-in-charge of Buntins, appeared in person and without counsel. The Board was represented by Joshua Hill. See transcript pages 6, 9, and 10.

- 3. All Board members participating in the decision of the Board were present throughout the disciplinary hearing.
- 4. The Board is an agency of the State of Missouri created and established pursuant to §338.110, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
- 5. Buntins is permitted by the Board as a Class A, retail pharmacy, and a Class C, long-term care pharmacy. Buntins permit number 003884 is and was at all times pertinent herein current and active. See transcript page 4.
- 6. The parties agreed that all the testimony in the case of <u>Missouri Board of Pharmacy v. William Buntin</u>, Case Number 2011-002696-V1, would be incorporated into the hearing involving Buntins. See pages 5-8 of the transcript.
- 7. On or about April 14, 2008, Buntins signed a Settlement Agreement which contained a Joint Stipulation of Facts, Joint Conclusions of Law, and a Joint Agreed Disciplinary Order and agreed to have its pharmacy permit placed on probation for a period of five (5) years. See Exhibit C.
- 8. The Board executed the Settlement Agreement on April 29, 2008, and all the terms of discipline therein became effective fifteen (15) days from that date. See Exhibits C.
- 9. The Settlement Agreement placed Respondent's pharmacy permit on probation for five (5) years and imposed terms of discipline which were agreed to be followed during the term of probation. See Exhibit C.
- 10. Pursuant to the Joint Agreed Disciplinary Order of the Settlement Agreement at paragraph 1.C, "Respondent shall comply with all provisions of Chapter 338 and Chapter 195; all applicable federal and state drug laws, rules and regulations; and all federal and state criminal laws. 'State' here includes the State of Missouri and all other states and territories of the United States." See Exhibit C.
- 11. Pursuant to the Joint Agreed Disciplinary Order of the Settlement Agreement at paragraph 4, the parties agreed that "If the Board determines that Respondent has violated a term or condition of this Settlement Agreement... the Board may elect to pursue any lawful remedies or procedures afforded it...". That paragraph also provides that "If any alleged violation of this Settlement Agreement occurred during

the disciplinary period, the Board may choose to conduct a hearing before it ... to determine whether a violation occurred and, if so, it may impose further discipline." See Exhibit C.

- 12. Each of the factual allegations in paragraphs 9-20, and the conclusions of law in paragraphs 27-33 in the case of <u>Missouri Board of Pharmacy v. William Buntin</u>, Case Number 2011-002696-V1, are specifically incorporated into this Order and are set forth below.
- 13. During an inspection on March 15, 2011, Buntins Pharmacy had outdated drugs in its pharmacy. See page 23 of the Buntin transcript. Buntin admitted he had outdated drugs in the pharmacy. See page 23 of the Buntin transcript. On April 6, 2011, those outdated drugs were still in the pharmacy, although the outdated drugs were stored in a bin within the pharmacy. See pages 23 and 24 of the Buntin transcript. Buntin explained that those outdated drugs were in the back of the pharmacy in totes, and that there was nothing to label those drugs as outdated. See page 24 of the Buntin transcript.
- 14. During an inspection on March 15, 2011, Buntins Pharmacy had testosterone powder, a controlled substance, that was not included in the controlled substance inventory for the pharmacy. See page 24 of the Buntin transcript. During a visit on April 6, 2011, that same substance remained in the pharmacy but was not included in the controlled substance inventory. See page 24 of the Buntin transcript.
- 15. During an inspection on March 15, 2011, an employee of Buntins Pharmacy who is not licensed or registered by the Board was behind the pharmacy counter. See pages 24-25 of the Buntin transcript. At the April 6, 2011, visit, that employee was not behind the counter. See page 25 of the Buntin transcript. Buntin offered Exhibit 1 into evidence, a statement signed by an employee of Buntins Pharmacy. The attorney for the Board objected to the exhibit as hearsay and that no proper foundation was made for introduction of the exhibit. See pages 44-46 of the Buntin transcript. The Board decided to rule on the objection in this Order. See page 46 of the transcript. The exhibit reads in its entirety: "On April 6th 2011 I signed a statement that said my duties had not changed since the first inspection and they hadn't. I was told in March that I couldn't come behind the counter to get deliveries &

trash until I became registered as a pharmacy tech. Deliveries & trash were brought to me at the front counter & I brought vials & supplies to the front counter until I became registered in May. This can be verified by techs Debbie Pollard, Jennifer Bowers & Erin Martel who brought me my deliveries & trash until May. I was not asked if I was still going behind the counter only had my duties changed." Exhibit 1 is signed by Scott Padgett. Mr. Padgett did not testify at the hearing, nor did any of the pharmacy technicians identified in Exhibit 1 testify. The exhibit is hearsay, an out-of-court statement offered for the truth of the matter asserted, and the objection is sustained. See http://blackslawdictionary.org/hearsay/ and http://criminal.findlaw.com/criminal- procedure/hearsay-evidence.html. However, even if that exhibit could be considered, it would not negate that on March 15, 2011, an unlicensed employee was behind the counter and in the licensed area of the pharmacy. It also would not address the variety of other violations that the hearing established that Buntin had committed. All Exhibit 1 does is establish that the employee states he was not behind the counter on April 6, 2011.

- 16. During an inspection on March 15, 2011, the Board's inspector provided Buntins Pharmacy with an Observation Report and Compliance Notice in which Buntins Pharmacy was to provide a written response by March 31, 2011. See Exhibit D, pages 1 and 2, and pages 39 and 40 of the Buntin transcript. Mr. Buntin did not provide a written response until April 6, 2011, under the mistaken impression he had thirty days to respond. See pages 40 and 41 of the Buntin transcript.
- 17. During an inspection on March 15, 2011, a review of the compounding log of Buntins Pharmacy revealed that the ingredients listed in the compounding log and listed on the label of a product called "magic mouthwash" did not contain the active or therapeutic ingredients. See pages 25 and 26 of the Buntin transcript.
- 18. During the inspections on March 15, 2011, and on April 6, 2011, Mr. Buntin had on display his expired pharmacist license. Exhibit E is a copy of the license on display on both inspection dates, even though it had expired. See page 26 of the Buntin transcript.
- 19. During the inspections on March 15, 2011, and on April 6, 2011, it was revealed that Buntins Pharmacy had been selling pseudoephedrine products without a

current Methamphetamine Epidemic Self-Certification. See page 26 of the Buntin transcript. Mr. Buntin testified that he had received the certification document on the date of the second inspection. See page 26 of the Buntin transcript.

- 20. A review of Buntins Pharmacy on March 15, 2011, revealed that it did not have an updated electronic record of shipments of controlled substances. See page 27 of the Buntin transcript.
- 21. As pharmacist-in-charge of Buntins Pharmacy, Buntin had the responsibility to ensure that the pharmacy was in compliance with state and federal laws applicable to pharmacies, including ensuring that the prescription area was restricted to authorized personnel, that all licenses be current and displayed in a conspicuous manner, that all procedures for handling, dispensing, and recordkeeping of the pharmacy be in compliance with state and federal law, that all prescriptions were labeled properly when dispensed from the pharmacy, and that no outdated drugs were maintained within the pharmacy. See pages 27 and 28 of the Buntin transcript.
- 22. Buntin testified that he "had become comfortable" because visits by Kevin Kinkade had not found any outdated drugs. See page 31 of the Buntin transcript.
- 23. Buntin testified that he plans on having a different person as pharmacist-in-charge by June 2012. See page 33 of the Buntin transcript.
- 24. Buntin admitted that the violations noted during the March 15, 2011, inspection, and April 6, 2011, follow-up visit violated the terms of the discipline in Exhibit C. See pages 55 and 56 of the Buntin transcript.
- 25. Paragraph 2 of the Joint Agreed Disciplinary Order of the Settlement Agreement provides: "...in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent. See Exhibit C.
- 26. Paragraph 3 of the Joint Agreed Disciplinary Order of the Settlement Agreement provides: "No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for a hearing before the Board in accordance with the provisions of Section 536, RSMo." See Exhibit

- C. The Board provided that hearing to Respondent and this Order is issued as a result of that hearing.
- 27. The failure of the owner/pharmacist-in-charge of Buntins to fulfill its responsibilities under the Settlement Agreement and under the laws of the state of Missouri are imputed to Buntins and resulted in a violation by Buntins of the Settlement Agreement.
- 28. In his closing remarks, Buntin stated that he had "fallen short" of his responsibilities and asked the Board to consider that he was going to bring in a new pharmacist-in-charge and apologized to the Board. See page 9 of the transcript.

CONCLUSIONS OF LAW

- 29. The Board has jurisdiction over this proceeding in that the Complaint presents a case in which the Board must determine whether or not a licensee has violated a condition or conditions of a settlement agreement issued by the Board. <u>State Board of Registration for the Healing Arts v. Masters</u>, 512 S.W.2d 150, 160-161 (Mo. App., K.C.D. 1974).
- 30. Maintaining outdated drugs in the active inventory violates 338.059(6), RSMo.
- 31. The failure of the inventory of the pharmacy to include all controlled substances violates 19 CSR 1.041(2) and 19 CSR 1.042(1)(A).
- 32. The evidence regarding the unlicensed person within the licensed pharmacy area is unclear what, if anything, he was doing in the area, and whether he was present as a matter of policy of Buntins Pharmacy. The Board does not impose additional discipline based upon this allegation.
- 33. Buntin's failure to properly label compounded substances, and in particular the product known as "magic mouthwash," violates 20 CSR 2220-2.400(7)(F).
- 34. By displaying William Buntin's expired license in the pharmacy, Buntins violated 20 CSR 2220-2.010(1) (K) and Section 338.080 RSMo.
- 35. By selling pseudoephedrine after the pharmacy's Methamphetamine Epidemic Self-Certification had expired, Buntins violated 21 U.S.C. 830 (e) (1) (B) (i) and 21 CFR 1314.40 (b).

36. Buntins failure to electronically record receipt of controlled substances violates 21 CFR 1305.22(g).

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- 37. The Board has jurisdiction to take disciplinary action against Respondent in that Respondent has violated the Settlement Agreement. See Sections 324.042 and 338.055.3 RSMo.
- 38. Respondent Buntins violated Chapter 338 and applicable federal and state drug laws, rules and regulations such that cause exists to discipline Respondent's license under Section 338.055.2 (5), (6), (13), and (15) RSMo.

DISCIPLINARY ORDER

THEREFORE, having considered all of the evidence before the Board, it is the ORDER of the Missouri Board of Pharmacy that the pharmacy permit issued to Buntins Pharmacy, numbered 003884, is hereby placed on PROBATION for five (5) years. This Order shall become effective ten (10) days from the date it is signed by the Executive Director, and replaces the Settlement Agreement dated April 29, 2008.

- 1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.
- 2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
- 3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.
- 4. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
- 5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Order becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

- 6. Respondent shall not serve as an intern training facility for interns.
- 7. Respondent shall select an independent pharmacist consultant for the purpose of reviewing and insuring the pharmacy's compliance with all applicable laws and regulations. The consultant shall be a Missouri licensed pharmacist whose license is current and not subject to disciplinary action by the Board. Within thirty (30) days of the beginning of probation Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval. Within thirty (30) days of the beginning of probation the said consultant shall visit the pharmacy, evaluate and provide corrective actions to remedy the issues outlined in this agreement/order. conduct a review for compliance with all applicable laws and regulations, and submit a written report to the Board office within thirty (30) days of the visit. The consultant's report shall include the suggested corrective actions, a timeline for the pharmacy to complete such corrective actions, items/areas reviewed for compliance with applicable laws and regulations during the visit, any deficiencies noted, and a plan to correct any deficiencies noted. The consultant shall then conduct visits and provide ongoing reports to the Board office on a three (3) month cycle for the first two years of probation and then on a six (6) month cycle thereafter. All consultant reports are due at the Board office within thirty (30) days of the consultant's visit to the pharmacy. The consultant shall be hired at Respondent's expense.
- 8. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.
- 9. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order/Agreement.
- 10. The parties to this Order understand that the Board of Pharmacy will maintain this Order as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.
- 11. Should Buntins violate any term or condition of this Order or any provision of Chapter 338, RSMo, the Board of Pharmacy may vacate the order of discipline

imposed herein and order such further or additional discipline as the Board deems appropriate, including, but not limited to, revocation, suspension, and/or probation against the pharmacy permit of Buntins. No additional order shall be entered by the Board pursuant to this paragraph of this Order without notice and an opportunity for hearing before the Board of Pharmacy as a contested case in accordance with the provisions of Chapter 536, RSMo.

- 12. Upon the expiration of the period of discipline, Buntins permit shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Buntins has violated any term or condition of this Order, or any provision of Chapter 338, RSMo, the Board, may in its discretion, vacate and set aside the terms and conditions of this Order and order such further or additional discipline as the Board deems appropriate.
- 13. If the Board determines that Buntins has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation.

ENTERED THIS 5 DAY OF MARCH, 2012

(BOARD SEAL)

KIMBERLY GRINSTON EXECUTIVE DIRECTOR

MISSOURI BOARD OF PHARMACY